DOCKET NO: 290074US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:
THOMAS OSTROWSKI, ET AL.	: EXAMINER: KEYS, ROSALYND
SERIAL NO: 10/578,874	:
FILED: 05/11/2006	: GROUP ART UNIT: 1621
FOR: METHOD FOR PRODUCING POLYETHER ALCOHOLS	:

APPEAL BRIEF (AMENDED)

This is an appeal to the Board of Patent Appeals and Interferences under 35 U.S.C. § 134 from the July 17, 2008, Final Rejection of Claims 1-11 of Application 10/578,874, filed May 11, 2006. A Notice of Appeal was timely filed on December 17, 2008, with a request for two months extension of time.

STATEMENT OF REAL PARTY IN INTEREST

The real party in interest in this appeal is BASF Aktiengesellschaft, having an address of Ludwigshafen, Germany 67056.

STATEMENT OF RELATED APPEALS AND INTERFERENCES

Appellant/Applicant, Appellant/Applicant's legal representative, and assignee, are aware of no appeals, interferences, judicial proceedings, or cases that are related to, directly affect or would be directly affected by, or have a bearing on the decision of the Board of Patent Appeals and Interferences in this appeal.

STATEMENT OF JURISDICTION

The Board of Patent Appeals and Interferences (Board) has jurisdiction under 35 U.S.C. § 134. This is an appeal to the Board from the Final Rejection of pending Claims 1-11, dated July 17, 2008. A Notice of Appeal was timely filed on December 17, 2008, with a request for two months extension of time. An Appeal Brief was timely filed on February 17, 2009, with no extension of time. Notification of Non-Compliant Appeal Brief (37 CFR 41.47)(PTOL-462) was mailed March 20, 2009, requiring Applicant to file an amended brief identifying the appealed claims in the Status of Claims section within ONE MONTH from the mailing date of the Notification. This Appeal Brief (Amended) properly identifying the appealed claims in the Status of Claims section was timely filed on April 16, 2009, with no extension of time.

STATUS OF CLAIMS

Claims 1-11 are pending in the Application..

Claims 1-11 stand rejected.

Claims 1-11 are appealed.

The rejection of Claims 1-11 is herein appealed.

STATUS OF AMENDMENTS

No amendments to Claims 1-11 on appeal have been entered or submitted after the Examiner's July 17, 2008, final rejection thereof. Applicant filed a request for reconsideration on October 17, 2008. In an Advisory Action dated November 20, 2008, the Examiner indicated that Applicant's request for reconsideration "has been considered but does NOT place the application in condition for allowance because: the Examiner believes that a prima facie case of anticipation has been established for the reasons of record."

SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent Claim 1 is directed to a "process for the continuous preparation of polyether alcohols by reaction of alkylene oxides with H-functional starter substances in the presence of DMC catalysts" (Claims Appendix, Claim 1). DMC catalysts are double metal cyanide catalysts which are preferred over catalysts conventionally employed in the preparation of polyether alcohols because they reduce the formation of undesirable unsaturated by-products (Specification (Spec.), page 1, lines 10-27). However, when using DMC catalysts, it is difficult to: (1) initiate the reaction between the alkylene oxides and the H-functional starter substances; and (2) establish steady-state conditions in the reactor (Spec., p. 2, ll. 15-16). The initial reaction is strongly exothermic. *Id.* The increasing heat of reaction is thought to poison, damage or otherwise stress DMC activity and either stop the

reaction or prevent the reaction from proceeding continuously to completion (Spec., p. 2, ll. 18-29). The inability to establish steady-state conditions is most problematic in processes for continuous preparation of polyether alcohols.

The process Applicant claims appears to solve the DMC catalyst deactivation problem and enables one skilled in the art to initiate and maintain continuous preparation of polyether alcohols using a DMC catalyst (Spec., p. 2, ll. 31-35).

The problem is solved in the beginning of the continous preparation process by (Spec., p. 2, l. 37, to p. 3, l. 20):

(a) placing initial charge material and DMC catalyst into a reactor;

(b) metering the rate of alkylene oxide addition to the reactor such that the rate required to maintain continuous operation of the reactor is reached from 100 to 3000 seconds of start of the reaction;

(c) metering the rate of starter substance addition to the reactor during or after step (b) such that the rate required to maintain continuous operation of the reactor is reached from 5 to 500 seconds of step (b); and

(d) continuously withdrawing product from the reactor when filled while metering the addition of starter substance, alkylene oxide, and DMC catalyst to the reactor in amounts sufficient to maintain the fill level of the reactor and its continuous operation.

By controlling the time, rate, and order of alkylene oxide, starter substance, and DMC catalyst addition and product withdrawal in accordance with the limitations of Applicant's claimed process, continuous preparation of polyether alcohol by reaction of alkylene oxide and H-function starter in the presence of a DMC catalyst can be achieved without deactivating the DMC catalyst and stopping or otherwise preventing the reaction from proceeding continuously.

GROUNDS OF REJECTION TO BE REVIEWED

Claims 1-11 stand finally rejected under 35 U.S.C. 102(b) as anticipated by O'Connor (O'Connor, et al., U.S. Patent 6,359,101, issued March 19, 2002).

ARGUMENT

Rejection of Claims 1-11 under 35 U.S.C. § 102(b) over O'Connor

Claims 1-11 stand or fall with Claim 1. All arguments relating to the merits of the rejection under 35 U.S.C. § 102 on appeal to the Board were presented in Applicant's responses dated October 17, 2008, and February 25, 2008, to the Examiner's first and final rejections of Claims 1-11 dated November 27, 2007 (First OA), and July 17, 2008 (Final OA), respectively. The Examiner's failure to explain the basis for her finding anticipation is a continuing source of error.

The Examiner has not satisfied the PTO's initial burden to establish that the process Applicant claims is unpatentable under 35 U.S.C. § 102(b) over O'Connor. The burden of proof is on the PTO to establish the factual basis for its rejections under 35 U.S.C. §§ 102 and 103. *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984); *In re Warner*, 379 F.2d 1011, 1016 (CCPA 1967). To support a rejection for unpatentability under 35 U.S.C. § 102, the Office must show that a single prior art reference, in this case O'Connor, describes every element of the process Applicant claims. *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990). To sustain an anticipation rejection under 35 U.S.C. § 102, the Examiner must initially establish that a single reference shows exactly what is claimed. Where the subject matter the prior art discloses and the subject matter claimed differ, there is no anticipation. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780 (Fed. Cir. 1985). Where the statutory basis for the rejection is Section 102, broad teachings and reasonable suggestions cannot remedy a deficient prior art disclosure. In this case the Examiner not only has erred in rejecting

Applicant's claims without explaining the basis for the anticipation rejection, but also has clearly erred in finding that O'Connor prima facie describes Applicant's claimed process in response to Applicant's arguments to the contrary.

1. Examiner erred by not explaining the factual basis for the § 102 rejection

In the first Office Action, the Examiner supported the rejection merely by stating, "O'Connor et al teach the instant invention (see entire disclosure, in particular column 6, lines 19-53; column 7, line 10 to column 15, line 48; note (3) under Table 3; and Table 6)" (First OA, p. 3, ¶ 6). The Examiner does not satisfy the Office's initial burden to establish a prima facie case of anticipation by requiring Applicant to read the entire disclosure and find some basis for the anticipation rejection.

In the second Office Action, the Examiner finally rejected Applicant's claims as anticipated by O'Connor "for the reasons given in the previous office action, mailed November 27, 2007" (Final OA, p. 2, ¶ 3). Again, Applicant was charged with searching O'Connor's disclosure and discovering the factual basis for the rejection. The Examiner has not satisfied the PTO's initial burden to show that O'Connor anticipates the process Applicant claims.

2. Examiner erred in finding that O'Connor describes the invention claimed

A. O'Connor does not explicitly describe the claimed process

O'Connor did not carry out a process for the continuous preparation of polyether alcohol by reacting alkylene oxide with H-functional starter substances in the presence of a DMC catalyst. O'Connor states that "A summary of all the relevant data generated is included in Tables 1-6" (O'Connor, col. 6, ll. 19-20). Table 1 is a report of data obtained from preliminary screening experiments designed to determine what level of DMC catalyst

concentration and which H-functional starters are most effective for initiating a reaction of alkylene oxide with an H-functional starter substance in the presence of a DMC catalyst. Time to Initiation was determined. O'Connor did not ever continuously prepare and withdraw polyether alcohol from a filled reactor (O'Connor, col. 15, l. 62, to col. 16, l. 56, Example 1 and Table 1).

With respect to Tables 2-6 O'Connor states (O'Connor, col. 6, ll. 41-52; emphasis added):

> The data in Table[s] 2-6 are based on the procedure of adding starter, PO [propylene oxide] and catalyst initially . . . with both the starter and PO initial levels varying as described in the table[s]. The reactor was rapidly heated . . . and the initiation time is defined as the time from 100°C. to polymerization initiation. Since we were exploring conditions to speed initiation, generally no additional PO was added to the reactor once the initial charge was consumed.

O'Connor expressly states that the information reported in Table 6 (O'Connor, cols. 21-24) is derived from a "Single Reactor Batch Process" (O'Connor, cols. 23-24, Examples 7 and 8; and col. 14, ll. 56-57). The reaction in Example 7 consumed all the PO and proceeded to completion in about 3 hours (O'Connor, col. 23, ll. 56-60). Regarding Example 8 having an initial charge of trimethylol propane, PO and DMC catalyst, O'Connor teaches (O'Connor, col. 24, ll. 48-56):

> The reaction commenced about 1 hour after the heating was started (about 20 minutes after reaching 125°C.) The exotherm peaked at 210°C. after another 15 minutes and all the initially charged PO was consumed in another 2 minutes. An additional 41.5 gms of PO were added and the reaction proceeded to completion in 15 minutes. The last PO was charged . . . and was consumed in another 1 hour.

O'Connor does not provide a single example of a process for the continuous preparation of polyether alcohols and most certainly does not provide an example of a process for the continuous preparation of polyether alcohols wherein the time, rate, and order of adding alkylene oxide, starter substance, and DMC catalyst and withdrawing product is controlled in accordance with the limitations of the process Applicant claims.

Nevertheless, a reference must be read for everything it discloses, and the scope of its disclosure cannot be limited to its examples. O'Connor is concerned with the factors relating to the difficulty with which the reaction between the alkylene oxides and the H-functional starter substances in the presence of a DMC catalyst is initiated. O'Connor generally appears to be unconcerned or less concerned with establishing the steady-state conditions in the reactor which are required in processes for the continous preparation of polyether alcohols by reacting alkylene oxides and the H-functional starter substances in the presence of a DMC catalyst. O'Connor's focus on the initial charge to the reactor is apparent from its claims and the following description of its invention (O'Connor, col. 5, ll. 48-61; emphasis added):

> We have surprisingly found that low molecular weight starters of groups (i) to (viii) can be directly initiated with DMC catalysts if the alcohol moieties are far enough apart o surrounded by other bulky groups so that the simultaneous interaction of both (all) hydroxyl groups with the catalyst is precluded. Additionally, if the structure of the starter is less favorable . . . modifications of the reaction conditions can force the initiation to occur especially by increasing the ratio of the number of moles of PO to moles of starter.

Consistent therewith, see also O'Connor's teachings at column 7, lines 31-36; col. 10, l. 65, to col. 11, l. 7; col. 11, ll. 65-67. There, O'Connor is concerned exclusively with initiating the reaction.

In the course of experimentation, however, O'Connor recognized the additional problems (O'Connor, col. 13, ll. 11-13), "In some instances the reaction stopped before all the PO was consumed." However, O'Connor's experimentation involved a single reactor batch process as indicated in the examples supporting Table 6. O'Connor's alternative solution to the uncontrollably exothermed reaction and catalyst deactivation is to control the initial PO to starter ratio and add additional PO until all the PO was consumed and the reaction was thereby completed (O'Connor, col. 13, ll. 17-40). An adequate description of a process for continuous preparation of polyether alcohols cannot be found anywhere in O'Connor.

At column 13, lines 40 to 53, O'Connor describes results achieved with different DMC catalysts (emphasis added):

> [T]hese polymerizations ceased before all the PO was consumed. With the control catalyst, it took over an hour to activate the catalyst, but once activated all the PO was consumed in about 5 minutes . . . . The catalyst was still active and additional PO was added . . . . The polyol preparation took place in one reactor over about 2.5 hour [sic] with no separate starter preparation required.

No process for continuous preparation of polyether alcohols is described there.

What then is the factual basis for the Examiner's finding that O'Connor anticipates the claimed process? Responding to Applicant's arguments, the Examiner states (Final OA, p. 3), "[T]he '101 patent [O'Connor] discloses both continuous and batch operation. See for example column 3, lines 49-56 and 63-67; column 10, lines 31-38; column 14, lines 26-50; and example 1."

We have already discussed the deficiencies of O'Connor's Example 1. At column 3, lines 49-56 and 63-67, O'Connor acknowledges that continuous processes of preparing polyether alcohols by reacting alkylene oxides and H-functional starter substances in the

presence of a DMC catalyst were known in the art. However, Applicant does not broadly claim a continuous process of preparing polyether alcohols by reacting alkylene oxides and H-functional starter substances in the presence of a DMC catalyst. Applicant claims a process for the continuous preparation of polyether alcohols by reacting alkylene oxides and H-functional starter substances in the presence of a DMC catalyst wherein the time, rate, and order of adding alkylene oxide, starter substance, and DMC catalyst and withdrawing product is specifically controlled and expressly limited. While the process O'Connor describes at column 3, line 60, to column 4, line 41, includes "polymerizing an epoxide in the presence of a double metal cyanide (DMC) catalyst and continuously added first starter wherein the epoxide and first starter are continuously added to the reactor during step (a)[,]" step (a) is expressly designed to "produce a polyol intermediate" which is thereafter reacted in step (b) "with additional epoxide and, optionally, additional DMC catalyst and a second starter . . . ." The process O'Connor describes in column 3 is not a continuous process. Moreover, O'Connor is not otherwise describing a process for the continuous preparation of polyether alcohols by reacting alkylene oxides and H-functional starter substances in the presence of a DMC catalyst wherein the time, rate, and order of adding alkylene oxide, starter substance, and DMC catalyst and withdrawing product is controlled as Applicant's Claim 1 requires.

Next, the Examiner points to O'Connor's disclosure at column 10, lines 31 to 38 (Final OA, p. 3). There O'Connor declares (O'Connor, col. 10, ll. 31-38; emphasis added):

> When compounds (i) and (viii) are used as <u>first</u> starters in a continuous process, a portion of them . . . may be initially added with the DMC catalyst before continuously adding the epoxide and the remainder of the first starter. Additionally, <u>after the polyol intermediate is formed</u>, the compounds (i) to (viii) or conventional starter material may be added as second starters in order to form the desired polyether polyol.

Consistent with the earlier teaching at columns 3 and 4, O'Connor's teaching at column 10, lines 31-38, appears to be related to a two step process which does not involve the continuous preparation of polyether alcohol and is not a process for the continuous preparation of polyether alcohols by reacting alkylene oxides and H-functional starter substances in the presence of a DMC catalyst wherein the time, rate, and order of adding alkylene oxide, starter substance, and DMC catalyst and withdrawing product are controlled as specified in Applicant's Claim 1.

Moreover, O'Connor's teachings are at best invitations to experiment. O'Connor does not describe a single process for the continuous preparation of polyether alcohol in a manner sufficient to have enabled one skilled in the art to make and use a process for the continuous preparation of polyether alcohols.

Finally, the Examiner points to O'Connor's teaching at column 14, lines 26-50 (Final OA, p. 3). There O'Connor teaches that its process "is an improvement over the patented ARCO continuous process technology" (O'Connor, col. 14, ll. 26-27). O'Connor suggests that, by using highly reactive starter materials, "the catalyst can be activated and then additional DMC catalyst, propylene oxide, water or propylene glycol could be fed into the reactor continuously while the product is continuously removed" (O'Connor, col. 14, ll. 27-36). While O'Connor suggests the possibility of employing its highly reactive starter materials in a process for continuous preparation of polyether alcohols, O'Connor does not teach persons having ordinary skill in the art how to carry out and maintain such a continuous process. Undue experimentation would have been required to determine the steady-state conditions and attain the steady-state conditions required to maintain a process for the continuous preparation of polyether alcohols from alkylene oxide and H-functional starter substances in the presence of a DMC catalyst. Only Applicant teaches a person having ordinary skill in the art how to do so. Undue experimentation would have been required to do

what O'Connor broadly suggests. O'Connor's non-enabling disclosure cannot anticipate the process Applicant claims. *Impax Labs., Inc. v. Aventis Pharm. Inc.*, ___ F.3d ____, 88 USPQ2d 1381, ____ (Fed. Cir. 2008)("to anticipate a claimed invention, a prior art reference must enable one of ordinary skill in the art to make the invention without undue experimentation")(Other Evidence in EVIDENCE APPENDIX, p. 3).

Nevertheless, the Examiner is not convinced. Employing impermissible hindsight, the Examiner points to Applicant's own Specification as support for the apparent argument that undue experimentation would not have been required to determine and achieve the steady-state conditions required for the continuous preparation of polyether alcohols (Final OA, p. 3). It is improper to point to Applicant's own inventive facility, or luck, as support for rejecting the patentability of the process Applicant claims. O'Connor does not describe a continuous process Applicant claims. Moreover, O'Connor does not reasonably suggest that a process for continuous preparation is feasible or likely to succeed. O'Connor merely states (O'Connor, col. 14, ll. 45-50; emphasis added):

> With more active diols . . . a 1 reactor CSTR (Continuous Stirred Tank Reactor) process is <u>possible</u>. Initiate, then feed PO, catalyst and starter while simultaneously removing product.

Possible processes and possibly successful processes, especially possibilities without guidance, direction, or factual basis for reasonably expecting success, require undue experimentation to anticipate success. O'Connor's possibilities are invitations to experiment. Applicant's invention is patentable thereover.

The Examiner argues that O'Connor well understood that, to achieve the steady-state conditions necessary for continuous operation, persons having ordinary skill in the art must control and stabilize the temperature and pressure in the reactor, control the reaction exotherm by lowering the PO to starter ratio, continuously add PO, starter, and catalyst, and

continuously withdraw product (Final OA, pp.3-4, bridging ¶). Nevertheless, while O'Connor recognizes the possibility of continuous processes (O'Connor, col. 14, ll. 45-50), O'Connor does not teach persons having ordinary skill in the art that success may be reasonably be expected and achieved without undue experimentation.

B. O'Connor does not implicitly describe the claimed process

Apparently recognizing that O'Connor falls short of describing all the limitations of Applicant's claimed process for continuous preparation of polyether alcohols by reacting alkylene oxides and H-functional starter substances in the presence of a DMC catalyst wherein the time, rate, and order of adding alkylene oxide, starter substance, and DMC catalyst and withdrawing product is controlled as specified in Applicant's Claim 1, the Examiner ultimately finds (Final OA, p. 4; emphasis added):

> The process of '101 patent is continuous, it achieves a steady-state by maintaining the PO addition and since the product is continuously removed it's [sic] properties no longer change with time. Thus, the instant metering times are inherently taught by the '101 patent. The '101 patent was able to achieve steady-state without catalyst deactivation (see example 2, example 6 and Table 6).

First, the Examiner improperly converts O'Connor's "possibility" into a description of a steady-state process for continuous preparation of polyether alcohol which is sufficient to place the continuous preparation process in the hands of the public. Then, the Examiner erroneously finds that the steady-state process for continuous preparation of polyether alcohol that O'Connor questionably describes inherently meets all the limitations of the continuous process Applicant claims.

The Examiner has not established that O'Connor would have enabled a person having ordinary skill in the art to make and use the "possibility" of a process for the continuous preparation of polyether alcohols by reacting alkylene oxide and active H-functional starter

substance in the presence of a DMC catalyst without undue experimentation. Moreover, even assuming that O'Connor's disclosure is marginally sufficient to describe just such a continuous process, the Examiner has not explained why that continuous process necessarily would have comprised, "at the beginning of the process" (Claims Appendix, Claim 1):

> b) metering in alkylene oxide so that the metering rate which is maintained for continuous operation of the reactor is reached in a time of from 100 to 3000 seconds, [and]
>
> c) metering in starter substance during or after step b) so that the metering rate which is maintained for continuous operation of the reactor is reached in a time of from 5 to 500 seconds[.]

Applicant's Specification recognizes processes for the continuous preparation of polyether alcohols by reacting alkylene oxide and active H-functional starter substance in the presence of a DMC catalyst which, at the beginning of the process, do not necessarily meter alkylene oxide and active H-functional starter substance in the time, at the rate, and in the order specified by Applicant's claims. In the Remarks/Argument Applicant submitted on October 17, 2008, Applicant pointed to page 4 of the Specification for the following disclosure (Spec., p. 4, ll. 15-21):

> When times to reach the metering rates in steps b) and c) are less than those specified, damage to the catalyst occurs, probably because of the high temperatures caused by the rapid metered addition and consequently spontaneous reaction of the propylene oxide. When the times specified are exceeded, it takes a long time for conditions in the reactor under which the target product is produced in a consistent quality to be reached, so that out-of-specification product is obtained in the start-up phase.

Applicant's Specification acknowledges that a process for continuous preparation of polyether alcohols can be achieved, albeit it takes a long time, by a process outside the scope

of Applicant's claims. Accordingly, there is no sound basis for the Examiner's finding of inherency.

In its Remarks/Argument of October 17, 2008 (p. 4), Applicant stated:

> *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981), [instructs,] the mere fact that a certain thing may result from a given set of circumstances is not sufficient to prove inherency. Inherency may not be established by probabilities or possibilities. Something that is inherent must inevitably be the result each and every time.

That statement appears to be a fair statement of the law. The fact that a certain result or characteristic may occur or may be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)(citations omitted). An invitation to experiment is not an inherent disclosure. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367 (Fed. Cir. 2004).

Finally, *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990), instructs:

> In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

In this case, the Examiner has not provided a basis in fact and/or technical reasoning to support a finding that the allegedly inherent characteristics of Applicant's claimed process necessarily flow from O'Connor's teachings. Therefore, the Examiner's rejection of

Applicant's claims based on the Examiner's finding of inherency cannot stand and should be reversed.

CONCLUSION

For the reasons stated, the Final Rejections of Claims 1-11 under 35 U.S.C. § 102(b) as anticipated by O'Connor should be reversed.

Respectfully submitted,

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CLAIMS APPENDIX

Claim 1 (Rejected): A process for the continuous preparation of polyether alcohols by reaction of alkylene oxides with H-functional starter substances in the presence of DMC catalysts, which comprises, at the beginning of the process

a) firstly placing initial charge material and DMC catalyst in a reactor,

b) metering in alkylene oxide so that the metering rate which is maintained for continuous operation of the reactor is reached in a time of from 100 to 3 000 seconds,

c) metering in starter substance during or after step b) so that the metering rate which is maintained for continuous operation of the reactor is reached in a time of from 5 to 500 seconds,

d) after the fill level in the reactor which is desired for continuous operation of the reactor has been reached, taking product off continuously from the reactor while at the same time metering in starter substance and alkylene oxides in such an amount that the fill level in the reactor remains constant and metering in DMC catalyst so that the catalyst concentration necessary for continuous operation of the reactor is maintained in the reactor.

Claim 2 (Rejected): A process as claimed in claim 1, wherein inert solvents or H-functional compounds are used as initial charge material.

Claim 3 (Rejected): A process as claimed in claim 1, wherein monofunctional or polyfunctional alcohols are used as initial charge material.

Claim 4 (Rejected): A process as claimed in claim 1, wherein polyfunctional reaction products of alcohols with alkylene oxides having a molecular weight of greater than 300 g/mol are used as initial charge material.

Claim 5 (Rejected): A process as claimed in claim 1, wherein the polyether alcohol which is the end product of the process is used as initial charge material.

Claim 6 (Rejected): A process as claimed in claim 1, wherein monofunctional or polyfunctional alcohols having a molecular weight of from 62 to 400 g/mol are used as starter substance.

Claim 7 (Rejected): A process as claimed in claim 1, wherein propylene oxide, butylene oxide, ethylene oxide or a mixture of at least two of the alkylene oxides mentioned is used as alkylene oxide.

Claim 8 (Rejected): A process as claimed in claim 1, wherein propylene oxide or a mixture of propylene oxide and ethylene oxide is used as alkylene oxide.

Claim 9 (Rejected): A process as claimed in claim 1, wherein the low molecular weight starter is heated to from 50 to 130°C before being metered into the reactor.

Claim 10 (Rejected): A process as claimed in claim 1, wherein the reactor is filled to a fill level of from 20 to 80% in step a).

Claim 11 (Rejected): A process as claimed in claim 1, wherein the concentration of the DMC catalyst at the beginning of the reaction is in the range from 50 to 500 ppm.

CLAIM SUPPORT AND DRAWING ANALYSIS SECTION

There are no drawings associated with the Application on appeal. Support for Claim 1 on appeal appears in the Specification at page 3, lines 5-20. All dependent claims stand or fall with Claim 1.

MEANS OR STEP PLUS FUNCTION ANALYSIS SECTION

There are no claims with means or step plus function language on appeal.

EVIDENCE SECTION

Affidavits and Declarations

No Affidavit or Declaration is relied upon in support of the patentability of the claims in this appeal.

Other Evidence

The following precedent is attached and relied upon in the Argument Section of this Appellant's Brief: *Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc.*, Docket No 2007-1513, pages 1-7, decided October 3, 2008 (Fed. Cir. 2008).

RELATED CASES SECTION

Appellant/Applicant, Appellant/Applicant's legal representative, and assignee, are aware of no appeals, interferences, or judicial proceedings that are related to, directly affect or would be directly affected by, or have a bearing on the decision of the Board of Patent Appeals and Interferences in this appeal.

United States Court of Appeals for the Federal Circuit

2007-1513

IMPAX LABORATORIES, INC.,

Plaintiff-Appellant,

v.

AVENTIS PHARMACEUTICALS INC.,

Defendant-Appellee.

C. Kyle Musgrove, Kenyon & Kenyon LLP, of Washington, DC, argued for plaintiff-appellant. With him on the brief were Michael M. Shen and Aimee N. Soucie, Steven J. Lee, of New York, New York, and Philip J. McCabe, of San Jose, California.

Paul H. Berghoff, McDonnell Boehnen Hulbert and Berghoff LLP, of Chicago, Illinois, argued for defendant-appellee. With him on the brief were James C. Gumina, Curt J. Whitenack, and Aaron F. Barkoff.

Appealed from: United States District Court for the District of Delaware

Judge Joseph J. Farnan, Jr.

United States Court of Appeals for the Federal Circuit

2007-1513

IMPAX LABORATORIES, INC.,

Plaintiff-Appellant,

v.

AVENTIS PHARMACEUTICALS INC.,

Defendant-Appellee.

Appeal from the United States District Court for the District of Delaware in case no. 02-CV-00581, Judge Joseph J. Farnan, Jr.

DECIDED: October 3, 2008

Before RADER, SCHALL, Circuit Judges, and ZOBEL, District Judge *.

RADER, Circuit Judge.

The United States District Court for the District of Delaware held that United States Patent No. 5,236,940 (the '940 patent) does not qualify as an enabling prior art reference and thus does not anticipate claims 1-5 of U.S. Patent No. 5,527,814 (the '814 patent). Because the trial court correctly determined that the '940 patent is not an enabling prior art reference and that it therefore does not anticipate claims 1-5 of the '814 patent, this court affirms.

I

The '814 patent relates to the use of riluzole to treat amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease). Aventis Pharmaceuticals Inc. (Aventis) owns the '814

* Honorable Rya W. Zobel, District Judge, United States District Court for the District of Massachusetts, sitting by designation.

patent and sells riluzole under the trade name RILUTEK. On May 16, 2001, Impax Laboratories, Inc. (Impax) filed with the Food and Drug Administration (FDA) an Abbreviated New Drug Application (ANDA) pursuant to 21 U.S.C. 355(j) seeking approval to market generic riluzole tablets. On June 25, 2002, Impax sued Aventis in the district of Delaware for a declaratory judgment that Impax did not infringe, induce infringement of, or contribute to the infringement of the '814 patent. In its suit, Impax alleged that the '814 patent was invalid and unenforceable.

After a bench trial, the district court determined that Impax did not prove that the '814 patent was unenforceable due to inequitable conduct nor show that claims 1-5 were anticipated by prior art. Impax Labs., Inc. v. Aventis Pharms. Inc., 333 F. Supp. 2d 265 (D. Del. 2004). On March 16, 2005, the court entered final judgment against Impax.

Impax appealed that decision. This court affirmed-in-part, vacated-in-part, and remanded to the district court. Impax Labs., Inc. v. Aventis Pharms. Inc., 468 F.3d 1366, 1384 (Fed. Cir. 2006). On remand, the trial court examined the asserted prior art, the '940 patent, for evidence that it enables the use of riluzole to treat ALS and thus qualifies as enabling prior art. Impax Labs., Inc. v. Aventis Pharms. Inc., 496 F. Supp. 2d 428, 433 (D. Del. 2007). In the event that it qualifies as enabling prior art, the trial court also received the opportunity to determine if the disclosure anticipates claims 1-5 of the '814 patent. Id. Addressing those questions, the district court determined that the '940 patent does not enable a person of ordinary skill in the art to treat ALS with riluzole and therefore does not anticipate claims 1-5 of the '814 patent. Id. Impax timely appealed the district court's remand decision to this court.

II

An issued patent enjoys a presumption of validity. Impax Labs., 468 F.3d at 1378. Thus, a party challenging patent validity has the burden to prove its case with clear and convincing evidence. Id. When the examiner considered the asserted prior art and basis for the validity challenge during patent prosecution, that burden becomes particularly heavy. See Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1467 (Fed. Cir. 1990).

In order to anticipate a claimed invention, a prior art reference must enable one of ordinary skill in the art to make the invention without undue experimentation. Finisar Corp. v. DirecTV Group, Inc., 523 F.3d 1323, 1336 (Fed. Cir. 2008) (citing In re Omeprazole Patent Litig., 483 F.3d 1364, 1379 (Fed. Cir. 2007)). In other words, the prior art must enable the claimed invention. Minn. Mining & Mfg. Co. v. Chemque, Inc. (3M), 303 F.3d 1294, 1301 (Fed. Cir. 2002). The "undue experimentation" component of that equation examines (1) the quantity of experimentation; (2) the amount of direction or guidance present; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

Whether a prior art reference is enabling presents a question of law based upon underlying factual findings. 3M, 303 F.3d at 1301. This court reviews the ultimate question of enablement without deference while reviewing the underlying factual inquiries for clear error. Elan Pharms., Inc. v. Mayo Found. Med. Educ. & Research, 346 F.3d 1051, 1054 (Fed. Cir. 2003). Under the clear error standard, the district

court's findings will not be overturned in the absence of a definite and firm conviction that a mistake has been made. Impax Labs., 468 F.3d at 1375.

A

The first time this case was before the district court, the trial court found that: (1) formula I encompasses a particularly large number of compounds; (2) riluzole was not meaningfully discussed in the treatment of medical conditions associated with the effects of glutamate; (3) the language of the '940 patent itself created "substantial uncertainty" regarding use of glutamate inhibiting compounds in the treatment of ALS; and (4) the language in the '940 patent discussing conditions implicating glutamate is speculative, at best. In other words, the district court found that the disclosure of the '940 patent did not put one of ordinary skill in the possession of the invention. See id. at 1384-85 (Rader, J., concurring-in-part). This court remanded for a specific determination on whether the '940 patent enables a person of ordinary skill in the art to treat ALS with riluzole without regard to the efficacy of such treatment. Id. at 1384.

On remand, the district court made additional factual findings on that specific question. The district court found that excessive experimentation would have been necessary to practice the invention. Specifically the trial court opined that formula I of the alleged prior art discloses hundreds or thousands of compounds and several diseases. Moreover, nothing in the '940 patent would direct one skilled in the art to recognize that riluzole could be used to treat ALS. The trial court rejected the notion that "the mere mention of riluzole is sufficient to put one skilled in the art in the possession of the claimed invention." Impax Labs., 496 F. Supp. 2d at 432.

The district court also did not find the dosage information in the disclosure to teach a proper treatment. Instead the trial court noted that "the dosage guidelines are broad and not specific to any of the hundreds of formula I compounds of the claimed invention or to any of the listed diseases." Id. at 433. Moreover, the '940 patent ties the dosing information to "the compounds of the invention" and specifically excludes riluzole from the invention. Id. at 432-33. Finally, the trial court also noted the absence of working examples.

In view of these findings, the district court found that one of ordinary skill in the pharmaceutical arts would have needed extensive experimentation to link riluzole with the treatment of ALS. Id. at 433. The district court then reached the ultimate conclusion that the '940 patent does not enable claims 1-5 of the '814 patent and thus, it is not anticipatory.

This court does not find error, let alone clear error, in the district court's factual findings. Weighing the Wands factors, the trial court's findings properly support its conclusion that an ordinarily skilled artisan would have needed to experiment unduly to gain possession of the invention. As shown by the trial court, the '940 patent's dosage guidelines are broad and general without sufficient direction or guidance to prescribe a treatment regimen. The alleged prior art also contains no working examples. Finally, nothing in the '940 patent would have led one of skill in the art to identify riluzole as a treatment for ALS. In sum, each component of the claimed invention—identifying riluzole as a treatment for ALS and devising dosage parameters—would require undue experimentation based on the teachings of the '940 patent. Because the '940 patent

does not enable a person of ordinary skill in the art to treat ALS with riluzole, it does not anticipate claims 1-5 of the '814 patent.

B

As this court explained during the first appeal, when an accused infringer asserts that a prior art patent anticipates specific patent claims, the infringer enjoys a presumption that the anticipating disclosure also enables the claimed invention. Impax Labs., 468 F.3d at 1382. However, the patentee may overcome that presumption with persuasive evidence showing that the prior art patent does not enable the claimed invention. Id. On appeal, Impax argues that the district court's silence regarding the initial presumption of enablement to both claimed and unclaimed material is reversible legal error. For this proposition, Impax cites this court's opinion in Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355-56 (Fed. Cir. 2003).

To the contrary, in Amgen, the district court placed an affirmative burden of proving the prior art reference's enablement of the claimed invention on the alleged infringer. Id. This court assigned error to that shifting of the burden. In this case, the district court correctly placed the burden of proving non-enablement on the patentee. The patentee then met that burden with persuasive evidence that the '940 patent does not enable claims 1-5 of the '814 patent. The district court did not need to specifically articulate its correct burden-shifting framework. In this case, as the district court found, the record shows sufficient evidence to overcome the presumption of enablement.

III

Because the district court applied the proper enablement standard and correctly determined that the '940 patent is not an enabling prior art reference and that it does not anticipate claims 1-5 of the '814 patent, this court affirms.

AFFIRMED